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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,052	03/24/2004	Richard S. Blumberg	B0801.70353US01	4208

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,052	BLUMBERG, RICHARD S.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed March 10, 2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant's arguments are substantially iterative of previous arguments in that Applicant argues that the examiner "mischaracterized" applicant's statements as an admission and further argues that a proper *prima facie* case has not been set forth. These arguments have been previously considered and are again found not to be persuasive.

Respectfully, Applicant's previous statements remain unambiguous as to the statement that "Therefore practicing one method for one tissue type is exactly the same as practicing it for another tissue type." The examiner properly withdrew the restriction and rejected all claims as *prima facie* obvious over the reference (Gregg). The reasoning is again reiterated below:

In the restriction requirement of August 1, 2006, Applicant was clearly advised that, "Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention." (*Restriction, page 6*).

In the response Applicant has stated, "The methods of the invention have one effect—inhibiting inflammation…The response is similar regardless of the tissue undergoing the

inflammation. The steps of the methods are identical, the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type. Therefore practicing one method for one tissue type is exactly the same as practicing it for another tissue type." (*Remarks, page 3*).

Thus Applicant has admitted on the record that the practice of "one method for tissue type is exactly the same as practicing it for another tissue type." Accordingly, the restriction requirement of August 1, 2006 is hereby withdrawn and this admission has been used in the rejection under 35 U.S.C. § 103(a) of the other invention. Additionally, in view of Applicants admission, that "the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type," the election of species is also hereby withdrawn.

Further, with regards to the obviousness rejection, because Applicant has admitted practicing the method in one tissue is exactly the same as practicing in another, the teachings of Gregg are properly relied upon in rejecting the claims under 35 USC § 103 in conjunction with the admission.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 80-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over GREGG (WO 98/50028 A1; PTO-892, 11/16/05).

The instant claims are generally drawn to inhibition of inflammation, inhibition of CD1-mediated inflammation, and inhibition of tissue inflammation.

Gregg teaches the elected species, identified as BMS-201,238 in a pharmaceutical composition (claim 10, page 47). It is noted by the examiner that BMS-201,038 (page 27), is the same compound by structure, and is claimed in a pharmaceutical composition (claim 21, page 55), and is identified in the specification as a 'most preferred' compound for practicing the invention (page 27).

Gregg teaches a method of lowering serum lipid levels, cholesterol and/or triglycerides, inhibiting and/or treating hyperlipidemia, hyperlipemia, hyperlipoproteinemia, hypercholesterolemia and/or hypertriglyceridemia, and/or preventing, inhibiting or treating atherosclerosis, pancreatitis, hyperglycemia or obesity in a mammalian species, comprising administering the compounds of claim 1 to a patient in need in a therapeutically effective amount (claims 22 and 23).

Atherosclerosis and diabetes (hyperglycemia) are art recognized to have inflammatory components (*e.g. REGAN-US Patent 6,080,763, column 3, lines 3-5; SALZMAN- US 2001/0053763 A1, page 3, [0040]*).

Gregg further teaches that the oral doses of the drug are 0.01 mg/kg to about 100 mg/kg, but preferably from 0.1 mg/kg to 75 mg/kg, and parenteral administration being preferred at

0.005 mg/ to about 8 mg/kg. (page 34). Additionally, it is noted that cardiac inflammation 'includes' atherosclerosis (*page 18, instant specification*).

Therefore, because Applicant has admitted on the record that the practice of "one method for tissue type is exactly the same as practicing it for another tissue type" it is deemed that the methods are obvious under 35 USC § 103(a). Additionally, because Applicant has admitted that "the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type", the methods being practiced with any inhibitor of MTP is obvious under 35 USC § 103(a).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654